AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C		

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 638-G
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

SONICA LLC 1544252
Attn: SHUAI XU
SONICA LLC 1900 GREENWOOD STRE
1900 GREENWOOD STREET, UNIT 8
EVANSTON IL 602013909

CODE 1544252 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00043

10B. DATED *(SEE ITEM 13)* 07/29/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
2019.1992019.25106

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-1 Alt. V Changes - Fixed Price (Apr 1984)
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 82-4003472
DUNS Number: 081039857
ASPR-19-03480 - Base Period funding for Sonica

A. In accordance with FAR 52.243-1 Alt. V Changes - Fixed Price (Apr 1984), the purpose of this modification is to make the following changes to the contract:

1) Revised Attachment 1 - Statement of Work to change language from patients with COPD to patients with any pulmonary issue. Changes are within scope and both parties mutually agreed to all changes.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Shuai Xu MD FAAD - CEO Sonica LLC	TROY G. FRANCIS

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)	4/23/2020	Troy G. Francis -S Digitally signed by Troy G. Francis -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001931480, cn=Troy G. Francis -S Date: 2020.04.23 15:46:29 -04'00' *(Signature of Contracting Officer)*	4/23/2020

NAME OF OFFEROR OR CONTRACTOR
SONICA LLC 1544252

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	B. This is a bilateral modification. The total dollar amount of all CLINs that are currently being performed under this contract remain unchanged. The parties bilaterally agree to the changes in the terms and conditions of the contract. All other terms and conditions of the contract remain unchanged. Delivery: 02/03/2020 Delivery Location Code: HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US Appr. Yr.: 2019 CAN: 1992019 Object Class: 25106 Period of Performance: 08/01/2019 to 03/31/2021 Change Item 1 to read as follows(amount shown is the obligated amount):				
1	ASPR-19-03480 - Base Period funding for Sonica Obligated Amount: $0.00				0.00

Attachment 1

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-18-100-SOL-00018

Title: Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting

Area of Interest #1 (ENACT)

Contractual Statement of Work

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to modify, augment, and validate our advanced, bio-integrated wireless sensor (ADAM) to monitor, predict, and track respiratory infections in high-risk populations and pulmonary patients.

The scope of work for this contract includes key engineering modifications and improvements to the ADAM sensor for deployment in this context. Specifically, this includes modifications to the underlying hardware and firmware software to accommodate 7-days of memory storage and battery life on a single charge. In addition, a new mobile application will be developed to allow for easy patient navigation and facilitate data collection. Finally, a single-arm prospective observational clinical study in the intended populations will be conducted. This study will evaluate the predictive value of the ADAM sensor outputs with clinically significant respiratory infections.

The R&D effort for [Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting] will progress in phases that cover the base performance segment to be labeled Contract Line Item Number (CLIN) 0001. The scope of work is broken into the following phases:

Phase I

AIM 1: Hardware Engineering Deliverables: we propose to extend the battery and memory storage of the existing ADAM (24 hours battery life and memory capacity) by 700% to 7 days battery life / memory capacity on a single charge to reduce user burden.

AIM 2: Software Engineering Deliverables: we propose to develop a custom mobile application specific to this engagement. This effort will occur concomitantly with AIM 1.

Phase II
AIM 3: Clinical Deliverables: at Northwestern University, we will conduct a single-arm, prospective clinical study to evaluate the predictive power of ADAM sensors for respiratory infection in high-risk populations and pulmonary patients. This will occur on a weekly basis for up to 52 weeks.

AIM 4: Data Analytics Deliverables: after completion of enrollment, we will deploy a range of biostatistical and machine learning techniques to correlate ADAM sensor outputs with clinical events recorded in the medical record and patient-reported outcomes via the custom mobile application. This will yield a set of novel algorithms specific to the ADAM sensor system that will be further validated in a follow-on, larger clinical study.

PHASE 1: Engineering Optimization of the ADAM System for Respiratory Infections

AIM 1: Hardware Augmentation of the ADAM Sensor System

We propose changes to our underlying circuitry and design to incorporate a 70 mAh battery that will have minimal impact on the overall dimensions and weight of the ADAM system. This includes identification and board testing of a larger capacity lithium ion battery, changes to the underlying circuit board firmware software changes that will maintain low-power operation. A larger memory capacity chip will also be implemented. The addition of a new battery will then require electrical safety validation for operation and charging. Safety testing will be conducted to ensure correct operation of the dual battery protection levels provided by two different battery management integrated circuits that follow JEITA standards. In addition, we will ensure minimal thermal load generation with operation and battery safety before pursuing clinical studies.

Objective: augment and modify the ADAM sensor for 7 days of continuous operation on a single charge.

Deliverable: 100 sets of the ADAM sensor with extended 7-day operation capabilities

Success criteria for completion of AIM 1:
-Successful manufacturing of 100 sets of ADAM sensors with extended 7-day operation capabilities
-Bench report testing of power performance of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of run time
-Bench report testing of memory capacity of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of memory time
-Bench report testing of thermal safety of ADAM sensors with <0% generating 5 °C after 24 hours of continuous operation

AIM 2: Custom Mobile Application Development

We propose to develop an highly simplified mobile application that facilitates data collection and upload. This application will allow for straight forward patient use including those of limited technological literacy. This will occur concomitantly with AIM 1. First, we will design a fully "clickable" user interface. Beta testing by Sonica engineers will be done to ensure easy to understand functionality. After a locked user interface, we will complete front-end application development for a new custom mobile application. This will include testing and validation with our backend system. Cloud-integration will also be tested where data from the mobile application directly is pushed to the cloud in a HIPAA-compliant manner.

Objective: develop a custom mobile application with cloud integration for the ADAM sensor to be used in the context of this program.

Deliverable: the deliverable includes design deliverables around a new mobile application, front-end mobile application development, integration with our existing backend code, and

Success criteria for completion of AIM 2:

-Completed user interface design with full click through functionality
-Fully functional mobile application with cloud integration capabilities
-Sandbox environment enabling full operation of the ADAM sensors with the new mobile application

1. **PHASE 2: Clinical Deployment of the ADAM System for Respiratory Infections**

AIM 3: Clinical Validation Testing

At Northwestern University, we will conduct a single-arm, prospective clinical study to evaluate the predictive power of ADAM sensors for respiratory infection in high-risk populations. In a cohort of pulmonary patients, we will deploy ADAM sensors for up to 52 weeks. A clinical research assistant will check-in with study subjects weekly with financial compensation given on a biweekly basis to boost engagement. Clinical diagnoses of respiratory infections will be determined via tracking of the patient's electronic medical record at Northwestern Memorial Health. Our power analysis suggest a target recruitment of 122 subjects to yield 10 instances of community acquired pneumonia (for instance) providing sensitivity and specificity scores for the ADAM sensor system..

Objective: the objective of this Aim is to establish critical validation data of the multi-modal data outputs of the ADAM sensor can monitor, predict, and track respiratory infections in our cohort. The secondary objective of this Aim is to demonstrate subject adherence to the protocol, and sensor usability in this population.

Deliverable: demonstration of successful sensor deployment, usability, and adherence by subject participants. On scheduled 6, 9, and 12 month interim data evaluations, we expect to provide preliminary evidence of the sensitivity, specificity, positive predictive value, and negative predictive value of ADAM sensor outputs for clinically diagnosed respiratory infections.

Success criteria for completion of AIM 3:
->70% weekly compliance with the ADAM sensor
-<20% data loss secondary to device failure

AIM 4: Data Analytics Development

We will deploy a range of biostatistical and machine learning techniques to correlate ADAM sensor outputs with clinical events recorded in the medical record and patient-reported outcomes via the custom mobile application. This will allow us to develop a predictive algorithm from the continuous data streams days or even weeks ahead of a clinically significant respiratory infection event that will be validated in a follow-on, larger clinical study. Our group has a wide range of techniques including continuous wavelet transforms, Fourier transforms, convolutional and recurrent neural networks, and multi-variate regression techniques. The finalized strategy will depend on the data collected.

Objective: development of novel algorithms using ADAM data outputs to assess clinically relevant respiratory infections.

Deliverable: Our deliverables here include predictive algorithms with adjustable confidence thresholds that can be deployed on a cloud-based user interface. The data generated will also warrant a pre-510(k) submission meeting with the FDA.

Success criteria for completion of AIM 4:
->70% of sensitivity for respiratory infection in a high-risk COPD cohort justifying further development and validation of the ADAM system in a larger, follow-on clinical study

3.1 PROGRAM MANAGEMENT

The contractor shall provide the following as outlined below and in the contract deliverables:

3.1.1 The overall management, integration, and coordination of all contract activities, including a

technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

3.1.2 A principal investigator (PI) or project manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

3.1.3 A project manager with responsibility for monitoring and tracking day-to- day progress and timelines; coordinating communication and project activities; costs incurred; and program management. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

3.1.4 A BARDA liaison with responsibility for effective communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR). The liaison may be the PM;

3.1.5 Administrative and legal staff capability with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract;

3.1.6 Administrative staff capability with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors;

3.1.7 Contract Review Meetings;

3.1.7.1 The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO and COR. Such meetings may include, but are not limited to, meeting of the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the contractor; and

3.1.7.2 The contractor shall participate in teleconferences every month with the CO and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

3.1.8 Gantt Chart

3.1.8.1 Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO and COR for review and comment. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance of the contract. The contractor shall include the key milestones and Go/No-Go Decision Gates.

3.1.8.2 Project Management Plan: In the management of this contract, the contractor shall utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes. The contractor shall submit the project progress management report to the CO and COR on a monthly

basis.

3.1.9 Risk Management Plan: The contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three months) in the monthly Project Status Report.

3.1.10 Monthly and Annual Reports: If requested, the contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW, WBS, IMS, and EVM or other Project Management Plan tool(s):

i. Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities;
ii. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
iii. Updated Risk Management Plan (every three months);
iv. Three-month rolling forecast of planned activities;
v. Progress of regulatory submissions

3.1.11 Data Management: The contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

3.1.12 Provide for the statistical design and analysis of data resulting from the research; and

3.1.13 Provide raw data or specific analyses of data generated with contract funding to the CO and COR, upon request.

3.2 REGULATORY

3.2.1 Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication;

3.2.2 Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages; and

3.2.3 Provide BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA, and (ii) final draft minutes of any informal meeting with the FDA.

4.1 FACILITIES, EQUIPMENT, & OTHER RESOURCES

The contractor shall provide equipment; facilities and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

4.1.1 The humane care and use of vertebrate animals;

4.1.2. The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.